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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,999	01/30/2004	Michael R.S. Hill	P-9091.06	7976
27581	7590	07/24/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			LAYNO, CARL HERNANDZ	
			ART UNIT	PAPER NUMBER

3766

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/768,999	Applicant(s) HILL ET AL.	
	Examiner Carl H. Layno	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-30, 33-35 and 38-46 is/are allowed.
- 6) ☒ Claim(s) 31, 32, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Acknowledgment is made of applicant's amendment, which was received by the Office on May 30, 2006.

2. Claims 1-46 are active and pending.

Specification

3. In view of the applicant's modifications to the specification, the Examiner is withdrawing the objections, which were made against the specification in the last Office action.

Claim Rejections - 35 USC § 102

4. Upon further reconsideration of applicant's arguments and amendments to the claims, the Examiner is withdrawing the 35 U.S.C 102(e) rejections of Matheny et al (US 5,651,378) and Taylor et al (US 6,381,499), which was made against claims 29, 30, 33-35, and 38-41 in the last Office action.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

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Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 31 and 32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45 and 58, respectively, of U.S. Patent No. 6,532,388. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims recite the use of a vagal nerve stimulation electrode in an endotracheal position to inhibit/manipulate the beating of a patient's heart. Applicant's claim 31 recites that it generally treats the heart by "intermittently starting and stopping electrical stimulation of the vagal nerve" whereas claim 45 of the '388 patent recites the specifics of twice stimulating the vagus nerve to inhibit heartbeats to perform a surgical procedure, then stopping stimulation of the vagus nerve to enable a resumption of normal heartbeats. Similarly, applicant's claim 32 and claim 58 of the '388 patent both recite the use of a vagal nerve stimulation electrode positioned in the esophagus to inhibit/manipulate the beating of a patient's heart. Again, applicant's claim 32 recites "intermittently starting and stopping electrical stimulation of the vagal nerve", whereas claim 58 of the '388 patent more specifically recites the treatment of a patient by first starting vagal nerve stimulation, then stopping it, then restarting it to enable a medical procedure.

7. Claims 31, 32, 36, and 37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5, and 10-15 of U.S. Patent No. 6,718,208. Although the conflicting claims are not identical, they are not patentably distinct from each other because the steps of applicant's claims 31 and 32 are also mentioned in a more specific way in the method steps of claims 1, 2, 5, and 13 in the '208 reference. Applicant's claims 36 and 37 recite details as in claims 31 and 32, but further disclose the use of drug treatments found in additional claims 10 and 11 or, 14 and 15, of the '208 reference.

Allowable Subject Matter

8. Claims 1-30, 33-35, and 38-46 are allowed.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Puskas (US 6,479,523) patent is cited for its pertinent vagal nerve and drug stimulation features. Unlike applicant's device, that of Puskas fails to disclose the capability of "automatically stopping" or "intermittently" starting or stopping nerve stimulation. In addition, its priority filing date (8/27/97) fails to predate the applicant's priority filing date (4/30/96).

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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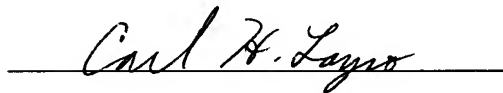
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on M-F between 9AM – 4PM and 8PM-10PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in cursive script, reading "Carl H. Layno", is written over a horizontal line.

CARL LAYNO
PRIMARY EXAMINER

CHL
7/19/2006